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VIA HAND DELIVERY

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Re: W.R. Grace Comments to Phase 2 Sampling Plan

Dear Mr. Peronard:

Enclosed please find W.R. Grace's Comments to the draft Phase 2 Sampling and Quality Assurance Project Plan for Libby, Montana.

If you have any questions, please call.

Very truly yours,

Kenneth W. Lund

KWL:cg
Enclosures

WR Grace Comments on Phase 2 QAPP: Libby, MT

General Comments

WR Grace continues to be concerned that USEPA does not have clear and scientifically supportable decision-making criteria for its work in Libby. The Agency continues to use risk assessment methodology that has not been peer reviewed either within or outside of the Agency. In addition, as discussed in greater detail below, the Agency apparently intends to make important risk-based decisions regarding the "relative hazard" associated with various activities in Libby based "on only a few samples." The stated rationale for ignoring sound statistical and scientific principles in the design of the sampling strategy, i.e., the "special exposure scenarios being evaluated in this study are only trial simulations of authentic exposures of area citizens," is unjustified. Unless a statistically valid sampling strategy is employed, together with validated risk assessment methodology, any "judgments" regarding risks to the public in Libby will be arbitrary and unfounded. While WR Grace is not opposed to appropriately conducted studies designed to improve exposure assessment in the Libby population, we object to the use of the preliminary results of this experimental study for making judgments regarding risks of indoor air in this community.

Any decisions made in Libby must be based on statistically sound sampling plans and scientifically supported, peer-reviewed and validated risk assessment methodology.

The QAPP is also noticably incomplete. By providing an incomplete document for public comment, USEPA does not allow adequate opportunity for comment. WR Grace reserves the right to comment on any new information added by EPA at a later time.

Specific Comments

A5. Problem Definition and Background

P.1 – WR Grace does not believe that "open pit" is an accurate characterization. In addition, the term "near" is ambiguous. The distance between the mine and the community should be stated accurately.

P.2 first paragraph – The QAPP references the Phase 1 work in Libby that "focused on collection of air samples from multiple indoor and outdoor locations around the community, along with samples of different potential sources of asbestos fibers in air." The QAPP then notes that "results from this phase of the investigation indicate that amphibole-type asbestos fibers are present in a number of environmental samples, including indoor air, dust, soil, and insulation." This discussion fails to note, however, that the air sampling previously performed did not exceed the target risk levels established by the USEPA in its Phase 1 QAPP. WR Grace reiterates its previously stated position that the USEPA has yet to produce scientifically supportable data indicating that the residents of Libby are currently experiencing unacceptable risk from ambient air. Furthermore, in spite of a significant sampling effort performed to date in indoor air locations around Libby, the USEPA has yet to come forward with evidence

indicating that Libby residents are at increased risk of disease from present day indoor air. There is nothing to indicate that Libby residents are currently being exposed to unacceptable risks from tremolite asbestos fibers in the air of their homes, workplaces, schools, public facilities or general community. As noted by Mr. Paul Peronard, USEPA On-Scene Coordinator during the September 2000 Asbestos Health Conference in Libby, "I don't see anything that indicates an ambient air problem in Libby right now." Regarding the results of indoor air data obtained to date in the homes and businesses of Libby, Mr. Peronard stated that using current standard EPA risk methods, "I would assign no risk to the data I've seen now." Documents such as the Phase 2 QAPP should fairly present the results of data obtained to date in Libby.

P.2 second paragraph – USEPA states that "there are potential problems which exist [with the sampling done to date] with regard to both the collection technique (stationary air monitors) and the analytical technique (TEM)". If such problems actually exist, they should have been addressed before the Phase 1 sampling was performed.

P.2 last paragraph – EPA states that "measurements of asbestos concentration based on TEM are difficult to convert to an equivalent concentration by PCM . . ." In the Phase 1, EPA forced the use of TEM. EPA should have addressed these issues in the Phase 1 sampling.

A6. Project/Task Description

P.3 Item 6 – As previously noted, the sampling protocol outlined in the Phase 2 QAPP is not adequately designed to collect statistically valid exposure data. Instead, "only a few" samples will be obtained. Furthermore, it is not clear what criteria USEPA will use in evaluating "risk estimates." Two methodologies are referenced; the currently validated IRIS methodology and the unvalidated Berman and Crump protocol. Only validated methodologies should be used for decision making in Libby. The stated intent to "compare and contrast the risk estimates derived by each of the two approaches" is inappropriate without clearly defined decision-making criteria established in advance of the study. For example, which risk assessment method will be considered to provide a valid indication of risk? Will the highest risk calculated by either method be used for decision-making, or the lowest? What is the "level of health concern" above which the USEPA intends to initiate risk-based activities? On page 9 the QAPP notes "USEPA considers excess lifetime risks that are below 1E-04 to 1E-06 to be sufficiently small that remedial action under Superfund is usually not warranted. Risks above 1E-04 are generally considered to warrant some sort of action or intervention, to the extent feasible." The USEPA already ignored much more clearly stated decision-making criterion when it ordered time-critical removal actions at the Export and Screening Plants, in spite of risk calculations demonstrating risks below predetermined levels. The failure of the Phase 2 QAPP to definitively state how the data will be used should be corrected if the Agency intends to go forward with this study. Our concern is further heightened by portions of the QAPP (pg.19) that appear to imply that for the "routine" activities to be evaluated in the study it will be impossible, even with samples that detect no fibers at all, to establish risk levels below 1E-04. One wonders why, if the Agency does not believe that the methods utilized can establish acceptable risks, this study is being proposed at all.

A7. Quality Objectives and Criteria for Measurement Data

FIRST OBJECTIVE, P.4 Step 2 – It is a long and well-established principle of industrial hygiene that task-specific exposures are most accurately assessed using personal, not area samples. Only air samples obtained in the breathing zone of the individuals whose activities are being evaluated can be considered to provide accurate assessments of exposure for those individuals or others performing the same activities. For example, in the Total Exposure Assessment Methodology (TEAM) studies performed by the USEPA in the 1980's (e.g., Wallace et al., 1986), personal exposures of individuals to volatile organic chemicals were assessed using personal monitors. The only exception was during nighttime periods, when the monitors were placed on a table or nightstand in the immediate vicinity of the individual while he/she slept.

FIRST OBJECTIVE, P.4 Step 3 – As previously discussed, it is invalid to ignore the generally recognized principle that "when variability is wide, more samples are needed to support risk management decisions," and instead base important judgments regarding risk on "only a few samples." We disagree, therefore, with USEPA's rationale that because the "special exposure scenarios being evaluated in this study are only trial simulations of authentic exposures of area citizens," statistical principles can be ignored. No risk decisions should be made from data that by design are not intended to provide a valid assessment of "authentic exposures" of the Libby population.

FIRST OBJECTIVE, P.5 Step 4 Number 1 – "Routine household activities (excluding active cleaning)". This item only describes routine household activities as those excluding active cleaning. It does not describe the actual types of routine household activities studied. Additional clarification is needed on the specific types of routine household activities referred to for this sampling such as watching television, cooking, eating dinner, reading, napping, etc. It is to be expected that routine household activities are different from family to family and different from day to day for each individual family. Will the routine household activities conducted during sampling be identical or different from house to house? Either way, how will the samplers ensure consistency between samples in each house and how will these samples accurately and consistently be compared to samples from other houses? How will the routine household activities conducted during sampling compare to the routine activities conducted in that household under normal non-sampling periods? Clear, concise methods and sampling plans are necessary to ensure that these samples are comparable 1) to normal activities of each family, and 2) to other families within the Libby community. In addition, there should be contingencies included for differences in distance in each house from the stationary to personal samples and corrections for house and room size.

For these and other reasons, it is unlikely that the few samples will allow "judgments about the relative hazard" of routine activities for the residents of Libby.

FIRST OBJECTIVE, P 5. Step 5 – It is difficult to imagine how the USEPA could conclude that "data from stationary monitors will be considered appropriate for individuals residing within the same house" in circumstances where USEPA considers these same monitors inappropriate for individuals actually performing the activities in

question. As previously noted, personal exposures to airborne substances are most accurately determined using personal samples.

SECOND OBJECTIVE, P.6 – It is unclear from the QAPP whether USEPA intends to analyze all samples using both NIOSH 7402 and ISO 10312 methods. This should be clarified in the protocol. Ideally, both TEM methods should be used in this portion of the study.

THIRD OBJECTIVE, P.8, Step 5 – USEPA should provide the rationale and underlying assumptions used to determine mean combined risks for lung cancer and mesothelioma from amphibole exposure averaged across gender and smoking status. For example, what proportion of the population was considered to be male versus female, and what proportion was considered to be smokers versus nonsmokers? On page 19 of the QAPP it states that it is assumed that 30% of the protocol structures are longer than 10 μm. Is this the same assumption used in deriving the combined unit risk factors, and if so, what is the basis for this assumption?

Furthermore, our comments regarding the use of the unvalidated Berman and Crump risk methodology notwithstanding, the authors of the Technical Background Document (Berman and Crump, 1999; pg. 5-39), note that "among long structures [greater than 5 μm in length], those shorter than 40 μm appear individually to contribute no more than a few percent of the potency of the structures longer than 40 μm." However, the authors subsequently decide on an "ad hoc" basis to establish risk equations for fibers less than or greater to 10 μm. Given the uncertainty in the ultimate outcome of the anticipated outside peer review of the Berman and Crump protocol, it would be appropriate to also calculate unit risks using fiber lengths of 5 – 40 μm and >40 μm. If, in fact, the USEPA intends to fully characterize the range of potential risks as determined with various risk methodologies it would be appropriate to include risks that would be calculated if experimental data on the effects of fiber size are more fully considered.

P.10 Table – This table further illustrates the extent that the QAPP Phase 2 methods and protocols are unclear. The initial round of sampling in Libby detected the presence of both chrysotile and amphibole asbestos in some of the homes in Libby. What types of fibers, amphibole or chrysotile, are referred to in this table? How many fibers of each type were detected at each home? To what extent do the indoor air homes and insulation homes overlap? The indoor air and insulation categories in this table are not mutually exclusive. Thus, the distinction should be made between previous amphibole asbestos detected in the presence of a home with vermiculite insulation from amphibole fibers detected in a home without vermiculite insulation. Since these two homes may imply different sources of amphibole asbestos, information of this type is vital to the clear understanding of the source of asbestos in and around Libby.

P.10 final paragraph – This section notes that "To the extent that sampling in different homes is sequential (rather than simultaneous), sampling will begin at the homes expected to have low levels of asbestos, followed by sampling at homes with higher levels of asbestos. This is done to minimize the chances of cross-contamination between homes." Sampling in a non-random pattern introduces a potential source of bias. For

example, for similar reasons, this non-random sampling pattern could result in inflated levels of asbestos seen in the homes sampled last. In addition, methods could vary slightly after the first few homes are sampled, i.e. the samplers have a better sense of how to conduct the sampling allowing for the sampling periods to progress more smoothly at later homes, etc. Even on a day-to-day basis, methods could vary slightly. Therefore, to ensure sound methodology, this protocol should include a random sampling plan.

P.11 first paragraph – WR Grace has two comments regarding this paragraph. First, as previously noted, indoor air sampling at Libby has not indicated that residents are at an increased risk. Mr. Peronard stated in September 2000 regarding the indoor air data obtained to date that "I would assign no risk to the data I've seen now." Second, EPA needs to assure that the persons performing the work have the necessary expertise.

P. 11 last paragraph and P. 13 first paragraph – There is no scientific reason to use Tyndall lighting during videotaping. The observation of "particles of dust in air" does not indicate whether such particles present any risk, are respirable, or are asbestos.

P. 13 final paragraph – "In order to help quantify the impact of the activity (simulated remodeling) on asbestos..." It is likely that the "simulated remodeling" included in this sentence is a typographical error since this paragraph discusses sampling during garden rototilling.

P.14 2nd table –Since it is unclear what routine household activities are included, it is not immediately clear why pre-activity and post-activity routine stationary air samples are not included. These samples should be collected for comparison purposes. Even if data of a similar nature were available from past samples, comparison to current data would not be the best science available. The addition of these samples entails little extra time and effort but could be invaluable for clear comparison purposes.

P.16 1st paragraph – "For the rototilling scenario, the RAM will be co-located with the downwind monitor." It is unclear if this protocol also includes upwind samples. If asbestos is detected in any rototilling sample, upwind samples would be vital to illustrating that no asbestos was present in the air prior to the initiation of the rototilling and thus any conclusion that the rototilling process released the asbestos from the soil. Without comparison of these upwind samples, the actual source of the asbestos in the downwind air cannot be proved.

B4. ANALYTICAL METHODS REQUIREMENTS

P.18 – Air and Dust Samples – The indirect preparation method for purposes of counting structures is inappropriate.

P.19 - Garden Soil and Insulation Samples – In this and other areas of the QAPP, the anticipated methods are not provided. This omission is particularly critical in regards to the methods anticipated for analysis of asbestos concentration in garden soils and insulation. Grace has stated previously (see June 9 and September 28, 2000 letters to EPA) that bulk soil determinations provide no relevant information regarding risk and that only analyses that provide information regarding "distribution of structure sizes,

shapes, and mineralogy in addition to the absolute concentration of structures" can be used for risk-based determination. This is obviously recognized by EPA since the Agency is in the process of designing and conducting a Performance Evaluation study aimed at developing and validating methods for analyzing asbestos in soil or other bulk materials using techniques and procedures that will allow for a risk-based assessment of the results.[1] If USEPA intends to utilize methods such as the NIOSH 9002 bulk analysis method using PLM, WR Grace again raises concerns regarding this issue. If the purpose of the Phase 2 studies is to provide information with which future risk based decisions can be made, it is imperative that methods for asbestos analysis in bulk materials (in this case garden soil and insulation materials) provide measurements of biologically relevant parameters. Total bulk analyses will not allow interpretation of the air data with respect to potential sources.

Although the Phase 1 monitoring did not indicate that indoor residential air poses an unacceptable risk from asbestos exposure, it is possible that future investigations specifically designed to exaggerate dust generation may result in the detection of asbestos fibers. Without a clear understanding regarding the presence and quantification of asbestos in attic insulation, and the biologically relevant parameters (e.g., fiber morphology), the results may not be indicative of potential risks associated with the presence of asbestos-containing insulation in Libby homes. For example, homes selected from former workers may have residual asbestos from activities that occurred during mining that are not in any way related to the presence of vermiculite insulation.

This critical flaw must be corrected for these investigations to have any relevance for future decisions. Furthermore, all references to methods and SOPs that are currently omitted must be evaluated before final comments on the Phase 2 QAPP can be completed.

General Comments on Sampling and Analytical Methodology

1. The ISO 10312 method, if used, should be modified to reflect the Berman Structure into separate classes at the time of analysis, and also identify all particulates counted that are greater than 5 microns in length with aspect ratio greater than 5 to 1 as cleavage, or asbestiform at the time of analysis.

2. In circumstances expected to have high dust concentrations, NIOSH 7400 prescribes filter observation and change out when visible dust can be detected on a filter examined with a flashlight. This should be done in addition to collecting samples with different flow rates.

3. It should be recognized that most fibers observed by PCM will not be amphibole asbestos.

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[1] Mr. Peronard refers to this study in his June 13, 2000 memorandum, opining that the results of the effort "will give a better tool for characterizing the asbestos content in solid matrices in Libby." (See AR Doc. No. 335006, p. 2)

4. PCM analysis should be performed using discriminate counting, which can be done by an experienced PCM analyst. This is permitted by OSHA and has been demonstrated in round robin testing to effectively discriminate between amphibole cleavage fragments and asbestos fibers.

5. Alternatively, TEM analysis should be performed consistent with NIOSH 7402 and the fraction of asbestos fibers found by TEM multiplied by the PCM count used to estimate asbestos concentration.

6. Asbestiform fiber morphological characteristics should be described as per EPA bulk sample methodology. TEM particles should be classified as cleavage, striated, splayed, curved or acicular as done by OSHA and others (e.g., Datachem).

7. Filters should be routinely checked and changed as necessary (after 8 hours for routine samplers).

8. If there is greater than 10% obstruction of particles on prepared samples they are to be considered overloaded using the ISO method criteria. This should be revised to 25% obstruction (ref EPA AHERA method). This will further reduce the number of samples that are to be prepared using indirect sample preparation techniques.

9. The magnifications for the TEM analysis should be specified if the ISO method is used for the analysis.

10. Analyzing the samples at magnifications of 20,000 X could bias the analysis in favor of smaller fibers with the stopping rule criteria specified. Hence, the risk assessment model for >10 micron fibers will be biased. Additional analyses using NIOSH 7402 methodology is suggested if the stopping rule criteria are to be based on asbestos fibers > 10 microns in length only.

11. Minimum TEM grid opening sizes should be specified so that limits of detection (LOD) models are consistent if multiple laboratories are performing the analysis. If this is not specified a total area analyzed criteria should be considered in lieu of number of grid openings.

12. The document specifies several Quality Control analyses including duplicate analyses by the same analyst, duplicate analyses by an independent analyst, field blanks, and other analyses. Precision, accuracy, completeness and other parameters are specified. Limits for these parameters must be included in the specifications.

13. It is anticipated that the selected laboratories will count particles observed on air or dust samples, which have an aspect ratio meeting the definition of protocol structures, by TEM and/or PCM (where applicable). The results should be presented in a tabular format separating the data into particle classes. These classes should include cleavage fragments, asbestiform fibers, and PCM equivalent fibers using the physical characteristics described by EPA and OSHA. All amphibole particles analyzed should be documented by hard copies of photographs, energy dispersive x-ray (EDS) spectra and selected area electron diffraction (SAED) patterns.